

REMARKS

Applicants respectfully request reconsideration. Claims 1-2, 14-15, 23-26 and 38-39 were previously pending in this application. Previously withdrawn claims 3-7, 9, 17, 20, 30-31, and 34-35 have been canceled herewith. By this amendment, Applicants are also canceling claims 15 and 39 without prejudice or disclaimer. Claims 1, 14, and 38 have been amended. As a result, claims 1-2, 14, 23-26, and 38 are pending for examination with claim 1 being an independent claim. No new matter has been added.

Claim Support

Claim 1 was amended to fully describe the antigenic fragment, the extracellular region of TgAMA-1, which consists essentially of an antigenic fragment of the sequence set forth as amino acids 23-456 of SEQ ID NO:1. Support for the amendment is found in the specification on page 4 lines 24-25, which describes the use of the extracellular domain as a vaccine. Example 1 describes the preparation of such a fragment, and production of an antibody that reacts with this fragment. For example, on page 29 line 30-31 the specification describes the transmembrane domain as being between the cleavage sites between residues 22 and 23 and residues 457 and 476. Page 30 line 18 describes the identification of “a 53-kDa fragment of TgAMA-1” that is demonstrated to be the N-terminal to the transmembrane domain in Example 1 page 32 lines 7-9. Support for the amendment of claim 38 is found in the specification at least on page 21, lines 5-10.

Rejections under 35 U.S.C. §112

Claims 1-2, 14-15, 23-26 and 38-39 stand rejected under 35 U.S.C. §112, first paragraph, as lacking written description. The examiner maintains that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the final office action the examiner has stated “there is no disclosure of antigenic fragment of SEQ ID NO:1...” and “No specific fragments were described in the specification in such a way as to reasonably convey to one skilled in the art...had possession of the claimed invention.”

Applicants have amended claim 1 to limit the antigenic fragment to one from the extracellular region of TgAMA-1, amino acids 23-456 of SEQ ID NO:1. The specification supports the use of extracellular domain fragments as vaccines for toxoplasmosis. An adequate written description of this embodiment is provided. It is believed that this amendment is sufficient to overcome the rejection of claim 1 and its dependent claims.

The Examiner further states that “applicant is claiming an isolated polypeptide comprising...antigenic fragment of SEQ.ID.NO: 1 and thus claiming an isolated polypeptide comprising any two amino acids as fragments without any function. Thus, the fragments as claimed are broader than the claimed SEQ.ID.NO:1.”

Applicant has amended claim 1 to specifically change the open language “comprising” to “consisting essentially of”. It is believed that this amendment is sufficient to clarify the scope of the claims and to overcome the rejection.

Claims 1-2, 14-15, 23-26 and 38-39 stand rejected under 35 U.S.C. §112, first paragraph as “the specification does not reasonably provide enablement for any isolated polypeptide comprising an antigenic fragment of SEQ ID NO:1”. The Examiner states that “the specification fails to indicate the biological activity of said fragments of SEQ ID NO:1...and further lacks any description of polypeptide SEQ ID NO:1 which acts as a vaccine.”

Applicants have amended claim 1 to specify the composition as a fragment of the extracellular region of Tg-AMA-1, amino acids 23-456 of SEQ ID NO:1. Fragments are disclosed in the specification at page 4 line 25 and the production and characterization of the fragment is described Example 1. Not only do the Applicants identify and describe the fragment in Example 1, an antibody which interacts with an epitope on this fragment is described.

The Examiner further suggests that the use of the term vaccine is not enabled. Applicants have amended the claims to remove the term “vaccine”.

Accordingly, withdrawal of the rejection of claims 1-2, 14, 23-26 and 38 under 35 U.S.C. §112 is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner rejected claim 1 under 35 U.S.C. §102 as being anticipated by Hehl et al. 1997, Accession number: AF010264 and Hehl et al. Accession number: O15681, 1998. The Examiner states that “the disclosed protein is 100% identical with the claimed protein, SEQ.ID.NO:1”


Claim 1 has been amended to replace the open language “comprising” with “consisting essentially of” to clarify that Applicants do not intend to claim the full length protein of SEQ.ID.NO:1. The presently claimed fragment was not previously known in the art to be the specific antigenic portion of the protein, and was not specified thus by Hehl et al.. It is believed that this amendment is sufficient to overcome the rejection. Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. §102 is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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